DENTSPLY

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K082973

JAN 29 2009

510(k) SUMMARY
for
Cavitron Steri-Mate Handpiece Sterile Lavage Kit

1. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
Telephone Number: 717-849-4229
Fax Number: 717-849-4343

Date Prepared: October 2, 2008

2. Device Name:

- Proprietary Name: Cavitron Steri-Mate Handpiece Sterile Lavage Kit
- Classification Name: Ultrasonic Scaler
- CFR Number: § 872.4850
- Device Class: Class II
- Product Code: ELC

3. Predicate Device:

Company: DENTSPLY International
Device: Steri-Mate Handpiece for Cavitron Jet
510(k) No.: K941392
Date Cleared: 05/23/1994

4. Description of Device:

The Cavitron® Steri-Mate® Handpiece Sterile Lavage Kit is an accessory for Cavitron® Ultrasonic Scalers that use the 30K Steri-Mate® Sterilizable Handpiece. This kit is intended to provide the clinician with a method to use sterile lavage

with a Cavitron® Ultrasonic Scaler. The kit consists of a pressurized infuser bag and a Steri-Mate Handpiece Adapter. The Pressurized Infuser bag can be hung from a standard IV pole or similar device. The Steri-Mate Handpiece Adapter is easily installed between the handpiece cable and the Steri-Mate Handpiece. The adapter does not affect the operation of the Cavitron® Unit or the Steri-Mate Handpiece.

5. Indications for Use:

The Steri-Mate Handpiece Sterile Lavage Kit is intended for use with a Cavitron Ultrasonic Scaler in general prophylaxis and periodontal treatments, and other areas of operative dentistry for the supragingival and subgingival removal of calculus, plaque and stain from teeth with sterile fluid delivery.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics

The Steri-Mate Handpiece Adapter is an accessory for the currently marketed Steri-Mate Handpiece for Cavitron Jet (K941392). The Adapter has been verified to function with the Steri-Mate Handpiece for Cavitron Jet. Additionally, comparative operations demonstrate that the Steri-Mate Handpiece Sterile Lavage Kit maintains the same performance to ultrasonically remove material from dental surfaces with the currently marketed device.

Non-Clinical Performance Data.

- The Steri-Mate Handpiece Sterile Lavage Kit contains no active electronic components. The Steri-Mate Handpiece Adapter allows the use of an external sterile water source. The source is not supplied with the product. Therefore, testing to IEC 60601-1 was considered not necessary based on engineering considerations.
- Validation of the ability of the Sterile Lavage Handpiece Adapter Kit to deliver sterile lavage was tested to the procedures described in the United States Pharmacopeia (31), National Formulary (26), 2008, Chapter <71> Sterility Test. Results have documented that the system is capable of delivering sterile solutions when assembled as directed in the Directions for Use.

Conclusion as to Substantial Equivalence

The results of testing demonstrate that the use of sterile fluid as a source of lavage is as safe, effective and performs as well to the currently-marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Helen Lewis
Director, Corporation Compliance and Regulatory Affairs
DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street Suite 60
York, Pennsylvania 17405-0872

JAN 29 2009

Re: K082973
Trade/Device Name: Steri-Mate Handpiece Sterile Lavage Kit
Regulation Number: 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: January 22, 2009
Received: January 23, 2009

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for
Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K082973

Device Name: Steri-Mate Handpiece Sterile Lavage Kit

Indications for Use:

The Cavitron Steri-Mate Handpiece Sterile Lavage Kit is indicated for use with the DENTSPLY Cavitron Ultrasonic Scaler in general prophylaxis and periodontal treatments, and other areas of operative dentistry for the supragingival and subgingival removal of calculus, plaque and stain from teeth with sterile fluid delivery.

Prescription Use __X__	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082973